

### **REMARKS**

This Amendment is in response to the Final Office Action dated November 18, 2003. Claims 1, 2, 4-15, 41, 42, and 44-73 are pending.

The Examiner has rejected claims 1, 2, 4-15, 41, 42, and 44-73 under §§ 102 and 103. Reconsideration of the rejection is respectfully requested in view of the following remarks.

#### **Claims Rejections - 35 USC §102**

The examiner rejected claims 1, 4-7, -11, 15, 41, 44-47, 49-51, 55-62, 64-66 and 68-73 under 35 U.S.C. § 102(e) over Langberg et al. US 6,402,781. Applicants respectfully disagree with the basis of the examiner's rejection of these claims for at least the reasons set forth below.

Independent claim 1 recites "a resilient mitral valve annulus device configured to be deformed and slidably received on the guide wire" and "a guide wire engaging structure" at at least one of its ends. As the examiner points out, the Langberg et al. reference does briefly describe a second embodiment "comparable" to the first embodiment "except that it does not contain an axially moveable forming element. Instead, a core of springy memory material such as nitinol or other NiTi alloy is pre-formed to have the required configuration." While the Langberg reference mentions that the device body 66 of its first embodiment may be provided with a guide wire lumen, its description of the second embodiment does not mention a guide wire or guide wire receiving structure. Specifically, the Langberg reference does not disclose whether the addition of the "springy memory material" core leaves any room for a guide wire or provides any guide wire engaging structure. In fact, Langberg's disclosure of the delivery of that embodiment refers only to pushing the device out of the delivery catheter, suggesting that no guide wire is needed. The Langberg et al. reference discloses neither a resilient device configured to be slidably received on a guide wire nor a guide wire engaging structure. That reference therefore cannot anticipate claims 1, 4-7, 9-11, 15 and 71-73 under § 102(e).

Claim 4 depends from claim 1 and recites that the guide wire engaging structure includes "a bore dimensioned to permit the guide wire to pass therethrough." As stated above, the

Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a guide wire bore. Langberg et al. therefore cannot anticipate claims 4-7 under § 102(e).

Claim 5 depends from claim 4 and recites a guide wire confining channel extending between the opposed ends of the device. Similarly, claim 7 depends from claim 6 and recites a guide wire confining channel extending between the opposed ends of the device. The Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a guide wire confining channel. Langberg et al. therefore cannot anticipate claims 5 or 7 under § 102(e).

Claim 11 depends from claim 1 and recites an elongated introducer configured to be slidably received on the guide wire proximal to the device. While the Langberg reference's description of its second embodiment refers to pushing the device out of a delivery catheter, the reference does not disclose or suggest the use of a guide wire or that the pushing element is at all configured to be slidably received on a guide wire. Langberg et al. therefore does not anticipate claim 11 under § 102(e).

Likewise, independent claim 41 recites an assembly including a guide wire means and a resilient mitral valve annulus reshaping means for sliding along the guide wire means in a deformed state, with the mitral valve annulus reshaping means including a guide wire engaging means at at least one of its opposed ends. As stated above, the Langberg et al. reference does not disclose whether the addition of a springy memory material core leaves any room for a guide wire means or provides any guide wire engaging means and suggests that no guide wire is even needed. The Langberg et al. reference discloses neither a resilient mitral valve annulus means for sliding along a guide wire nor a guide wire engaging means. That reference therefore cannot anticipate claims 41, 44-47, 49-51 and 55 under § 102(e).

Claim 44 depends from claim 41 and recites that the guide wire engaging means include a bore dimensioned to permit the guide wire to pass therethrough. As stated above, the Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a guide wire bore. Langberg et al. therefore cannot anticipate claims 44-47 under § 102(e).

Claim 45 depends from claim 44 and recites channel means extending between the opposed ends for confining the guide wire means. The Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a channel means for confining a guide wire means. Langberg et al. therefore cannot anticipate claim 45 under § 102(e).

Claim 47 depends from claim 46 and recites guide wire channel means extending between the opposed ends and aligned with the bore for confining the guide wire means. The Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a guide wire channel means for confining a guide wire means. Langberg et al. therefore cannot anticipate claim 47 under § 102(e).

Claim 51 depends from claim 41 and recites an elongated introducer means configured to be slidably received on the guide wire means proximal to the reshaping means for pushing the reshaping means along the guide wire means. As stated above, while the Langberg reference's description of its second embodiment refers to pushing the device out of a delivery catheter, the reference does not disclose or suggest the use of a guide wire mean or that the pushing element is at all configured to be slidably received on a guide wire means for pushing the device along a guide wire means. Langberg et al. therefore does not anticipate claim 11 under § 102(e).

Independent claim 56 recites a device comprising a resilient member, the device having a channel extending between its distal and proximal ends and a bore through one of the ends, the channel and the bore permitting the device to be slidably received on a guide wire. Once again, the Langberg et al. reference does not disclose whether the addition of a springy memory material core leaves any room for a channel or a bore permitting the use of a guide wire and suggests that no guide wire is even needed. Langberg et al. therefore does not anticipate claims 56 and 68-70 under § 102(e).

Independent claim 57 recites a device formed from resilient material and having a guide wire receiving structure that slidably mounts the device on a guide wire. As stated repeatedly above, the Langberg et al. reference does not disclose whether the addition of a springy memory material core leaves any room for a guide wire receiving structure and suggests that no guide wire is

even needed. Langberg et al. therefore does not anticipate claims 57-62, 64-66 and 68-73 under § 102(e).

Claim 58 depends from claim 57 and recites that the guide wire receiving structure includes a bore dimensioned to permit a guide wire to pass therethrough. The Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a guide wire bore. Langberg et al. therefore cannot anticipate claims 58-61 under § 102(e).

Claim 60 recites that the guide wire receiving structure includes a guide wire confining channel extending between opposed ends of the device. The Langberg et al. reference does not suggest that its core of springy memory material leaves any room for a guide wire confining channel. Langberg et al. therefore cannot anticipate claims 60 and 61 under § 102(e).

### **Claims Rejections - 35 USC §103**

#### **Rejection of claims 2, 8, 12, 48 and 52 under 35 U.S.C. § 103(a)**

The examiner rejected claims 2, 8, 12, 42, 48 and 52 under 35 U.S.C. § 103(a) as being unpatentable over the Langberg et al. reference in view of de Toledo et al. US 4,830,023. The de Toledo et al. reference does not make up for the deficiencies in the Langberg et al. disclosure, however. Applicants therefore respectfully disagree with the examiner's rejection of these claims.

Specifically, claims 2, 8 and 12 depend from claim 1. Neither the Langberg reference nor the de Toledo reference discloses or suggests a resilient device configured to be slidingly received on a guide wire or a guide wire engaging structure as required by claim 1. Claims 2, 8 and 12 are therefore allowable over the combination of the Langberg and de Toledo references under § 103(a).

Similarly, claims 48 and 52 depend from claim 41. Neither the Langberg reference nor the de Toledo reference discloses or suggests an assembly including a guide wire means and a resilient mitral valve annulus reshaping means for sliding along the guide wire means in a deformed state, with the mitral valve annulus reshaping means including a guide wire engaging means at at

least one of its opposed ends, as required by claim 41. Claims 48 and 52 are therefore allowable over the combination of the Langberg and de Toledo references under § 103(a).

Rejection of claims 13, 14, 53, 54, 63 and 67 under 35 U.S.C. § 103(a)

The examiner rejected claims 13, 14, 53, 54, 63 and 67 under 35 U.S.C. § 103(a) as being unpatentable over Langberg et al. in view of Taylor et al. US 2002/0183835. The Taylor et al. reference, however does not make up for the disclosure deficiencies of the Langberg et al. reference.

Claims 13 and 14 ultimately depend from claim 1. Neither the Langberg reference nor the Taylor reference discloses or suggests a resilient device configured to be slidably received on a guide wire or a guide wire engaging structure as required by claim 1. Claims 13 and 14 are therefore allowable over the combination of the Langberg and Taylor references under § 103(a).

Similarly, claims 53 and 54 ultimately depend from claim 41. Neither the Langberg reference nor the Taylor reference discloses or suggests an assembly including a guide wire means and a resilient mitral valve annulus reshaping means for sliding along the guide wire means in a deformed state, with the mitral valve annulus reshaping means including a guide wire engaging means at at least one of its opposed ends, as required by claim 41. Claims 53 and 54 are therefore allowable over the combination of the Langberg and Taylor references under § 103(a).

Claim 63 depends from claim 57. Neither the Langberg reference nor the Taylor reference discloses or suggests whether the springy memory material core of Langberg's second embodiment leaves any room for a guide wire receiving structure. Claim 63 is therefore allowable over the combination of the Langberg and Taylor references under § 103(a).

Finally, claim 67 depends from claim 56. Neither the Langberg reference nor the Taylor reference discloses or suggests whether Langberg's addition of a springy memory material core leaves any room for a channel or a bore permitting the use of a guide wire. Claim 67 is therefore allowable over the combination of the Langberg and Taylor references under § 103(a).

Appl. No. 09/855,945  
Amdt. Dated January 16, 2004  
Reply to Office Action of November 18, 2003

**Information Disclosure Statement**

The examiner did not consider the references cited on the Information Disclosure Statement filed on June 23, 2003 due to its failure to comply with 37 CFR § 1.97. A new Information Disclosure Statement is enclosed which is being filed before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR § 1.114 and which therefore complies with the requirements of 37 CFR § 1.97. Consideration of the references cited therein is respectfully requested.

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**CONCLUSION**

Applicants submit that the instant application is in condition for allowance. Please continue to direct all questions and correspondence to the attorneys of record in this case:

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No.29912.702.201).

Respectfully submitted,

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